PATTON BOGGS LLP
ATTORNEYS AT LAW

2550 M Street, NW
Washington, DC 20037-1350
202-457-6000
Facsimile 202-457-6315
www.pattonboggs.com

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July 31, 2002

Daniel A. Kracov
(202) 457-5623
dkracov@pattonboggs.com

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061, HFA-305
Rockville, MD 20852

Re: Docket Nos. 01P-0571, 02P-0206; Comments on the Citizen Petitions Filed by the National Center for Tobacco-Free Kids, et al. and the Society for Research on Nicotine and Tobacco Seeking Food and Drug Administration Regulation of Vector Tobacco's Omni® Cigarette Product

Dear Sir/Madam :

Enclosed please find the comments of Vector Tobacco Inc. on the above-referenced Citizen Petitions concerning Vector Tobacco's Omni® Cigarette Product.

Sincerely,

Daniel A. Kracov

Counsel to Vector Tobacco, Inc.

Enclosure

01P-0571 C2

BEFORE THE FOOD AND DRUG ADMINISTRATION

Citizen Petitions Filed by the National Center for Tobacco-Free Kids, et al. and the Society for Research on Nicotine and Tobacco Seeking Food and Drug Administration Regulation of Vector Tobacco's Omni® Cigarette Product	)	**Docket Nos. 01P-0571, 02P-0206**

Comments of Vector Tobacco Inc.

Patton Boggs, LLP
2550 M Street, N.W.
Washington, D.C. 20037
Telephone: (202) 457-5623
Facsimile: (202) 457-6315

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Comments of Vector Tobacco Inc. (Docket Nos. 01P-0571, 02P-0206)

On behalf of our client, Vector Tobacco Inc. ("Vector"), we hereby submit Vector's response to the above-referenced Petitions filed with the Food and Drug Administration ("FDA" or "Agency") by the National Center for Tobacco-Free Kids and 17 other groups on December 18, 2001, and the Society for Research on Nicotine and Tobacco on April 23, 2002.

The petitioners argue, once again, that cigarettes are "drugs" within the meaning of the Federal Food, Drug, and Cosmetic Act ("FFDCA" or "the Act"), and therefore should be subject to FDA jurisdiction. In doing so, however, the petitioners resurrect arguments that have been repeatedly rejected by the FDA, Congress, and the judiciary. As the agency is well aware, in the Supreme Court decision *FDA v. Brown & Williamson*[1] the Supreme Court held that cigarettes as customarily marketed are not subject to FDA jurisdiction. The Supreme Court emphasized that Congress precluded FDA's jurisdiction to regulate tobacco products in the absence of the type of claims that led to FDA jurisdiction in the past (i.e., therapeutic claims such as claims that cigarettes can help one lose weight, prevent colds, or inhibit infections).[2]

Omni cigarettes bear no therapeutic claims, and are subject to the same regulatory status as traditional "low tar" and "light" tobacco products that have been marketed in the United States for over 50 years (and which are not, and never have been, subject to FDA jurisdiction). As explained herein, if FDA were to assert jurisdiction over such cigarettes, it would do so contrary to Congressional dictate, Supreme Court holding, and past FDA precedent on this issue. [3] Accordingly, we hereby request that the Secretary reject the Petitions.

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[1] *Brown & Williamson*, 529 U.S. 120, 120 S. Ct. 1291 (2000).

[2] *Id.* at 150-53 (citing *ASH v. Harris*, 655 F.2d 236, 239 n.7 (C.A.D.C. 1980), citing *United States v. 46 Cartons more or less, containing Fairfax Cigarettes*, 133 F. Supp. 336 (D. N.J. 1953) ("*Fairfax*"), and *United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847 (D. N.J. 1959) ("*Trim Reducing-Aid*")). The Supreme Court cited two decisions that upheld FDA jurisdiction over products that contain tobacco, and in both of those decisions therapeutic claims – such as claims to prevent colds, lose weight, or inhibit infections – were made.

[3] In the absence of FDA jurisdiction, Omni, like other traditional cigarettes, would still be subject to stringent tobacco-specific legislation enacted by Congress. *See* Section V. B., infra.

I. Omni Background.

A. Omni is a Traditional Cigarette, Promoted for Specific Product Attributes.

Omni cigarettes are made from conventional tobacco that has been treated to reduce specific carcinogens in the smoke, notably PAHs (polycyclic aromatic hydrocarbons), nitrosamines, and catechol. Omni is composed of tobacco and tastes, smokes, and burns like a conventional cigarette.[4] Omni is marketed and promoted as a traditional, premium cigarette. The cost of a carton of Omni is comparable to the cost of a carton of the leading premium cigarettes. The product package and advertising both contain mandatory Surgeon General's Warnings – as required for all conventional cigarettes.

As explained in detail herein, cigarette manufacturers have promoted cigarettes based upon their product attributes – including reductions in constituents – for over 50 years. "Low tar" and "light" cigarettes have never been subject to FDA jurisdiction, as such claims do not constitute "therapeutic claims" (i.e., claims to prevent disease) but rather merely describe the composition and attributes of tobacco smoke. Representations regarding the reduction of a smoke component, such as "reduced carcinogens," cannot legally constitute a therapeutic claim subject to FDA jurisdiction. By contrast, in the only situations where the FDA has successfully asserted jurisdiction over cigarettes, the cigarette products were specifically promoted as being beneficial in preventing disease and/or to lose weight (i.e., alleging that tobacco acts as a weight-reduction drug).

B. Omni Labeling and Advertising.

The petitioners, failing to acknowledge the care and deliberation taken by Vector to develop fair and accurate product labels and advertising, have selectively identified certain aspects of Omni advertisements while conveniently ignoring other prominent aspects in order to provide a skewed representation of the product. As explained below, a fair reading of Omni advertisements makes clear Omni is a traditional cigarette to be used for smoking enjoyment that – like "low tar" and light" cigarettes – emphasizes particular product attributes (i.e., reduction of certain carcinogens).

As with most cigarettes, Omni is first and foremost marketed based upon its favorable taste profile. Indeed, in Vector's print advertising campaign for Omni, each ad features the claim: "Premium Taste."[5] In each Omni advertisement, the largest print aside from the brand name is the line "Reduced Carcinogens. Premium Taste.™" Most Omni print advertisements to date largely consist of a picture, portraying usually a single person and sometimes a couple evidently enjoying smoking, clearly conveying that the purpose of the product is for smoking pleasure.[6]

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[4] *Vector Tobacco's New Reduced Carcinogen Cigarette Scores High in Taste Tests Against Leading Premium Brand*, press release dated Sept. 28, 2001. (*See* Attachment A.)

[5] *See* Attachment B.

[6] FDA Commissioner Edwards, during 1972 Congressional Hearings, stated that "cigarettes recommended for smoking pleasure are beyond the Federal Food, Drug, and Cosmetic Act." Quoted in *Brown & Williamson* at 151.

Underneath the tag line of "Reduced Carcinogens. Premium Taste™", in type larger than that in the Surgeon General's Warning, is a straightforward statement of the constituents that are reduced: "Introducing the first premium cigarette created to significantly reduce carcinogenic PAHs, nitrosamines, and catechols, which are the major causes of lung cancer in smokers." In addition to the Surgeon General's Warning, each Omni advertisement includes an additional, voluntary boxed warning of a size and prominence virtually identical to the mandatory Surgeon General's Warning. By using the same size and prominence as the Surgeon General's Warning, Vector ensured that the voluntary warning would be read by consumers and affect consumer purchasing decisions. It provides:

> WARNING: Smoking is addictive and dangerous to your health. Reductions in carcinogens (PAHs, nitrosamines, and catechols) have NOT been proven to result in a safer cigarette. This product produces tar, carbon monoxide, and other harmful by-products, including increased levels of nitric oxide.

As noted, this voluntary warning is surrounded by a box of the same size as the mandatory Surgeon General's Warning, and is typically displayed on the same plane as the mandatory warning. In addition to the voluntary warning, a voluntary explanatory statement is also provided, clarifying the "Reduced carcinogens" statement as follows: "Reductions are in comparison to the leading similar brand styles." Nowhere in any Omni advertisement is it claimed, explicitly or implicitly, that Omni provides a therapeutic benefit.

The Omni package,[7] not discussed by the petitioners, also bears straightforward statements along with a clear and prominent voluntary warning. The back panel bears the following language: "Omni is the first premium cigarette created to significantly reduce carcinogenic PAHs, nitrosamines, and catechols, which are the major causes of lung cancer in smokers." In addition to the Surgeon General's Warning, a voluntary warning identical to the warning in all of the print advertisements is also included:

> WARNING: Smoking is addictive and dangerous to your health. Reductions in carcinogens (PAHs, nitrosamines, and catechols) have NOT been proven to result in a safer cigarette. This product produces tar, carbon monoxide, and other harmful by-products, including increased levels of nitric oxide.

Thus, nowhere in any Omni advertisement or labeling is it claimed, explicitly or implicitly, that Omni provides a therapeutic benefit.

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[7] *See* Attachment C.

II. Cigarette Products Lacking Therapeutic Claims, Such As Omni, Are Not Subject to FDA Jurisdiction.

A. The Supreme Court's Decision in *Brown & Williamson* Precludes Broad FDA Jurisdiction over Tobacco Products.

In March of 2000, the Supreme Court, in *FDA v. Brown & Williamson*, held that FDA does not have jurisdiction over tobacco products.[8] The Supreme Court documented the FDA's historical and repeated position that the agency does not have jurisdiction over tobacco products. The Supreme Court observed that:

> To the extent the agency's position could be characterized as equivocal, it was only with respect to the well-established exception of when the manufacturer makes express claims of therapeutic benefit. . . . Thus, what Congress ratified was the FDA's plain and resolute position that the FDCA gives the agency no authority to regulate tobacco products as customarily marketed.[9]

After reviewing the statutory definitions of a "drug" and "device," the Supreme Court briefly summarized the FDA's 1995 proposed rule and the 1996 final rule imposing restrictions on cigarettes and smokeless tobacco products. The Supreme Court held FDA's rulemaking regarding tobacco to be unlawful, and refused to permit FDA's broad assertion of jurisdiction over tobacco products. The Supreme Court documented in great detail the history of tobacco legislation, as well as the FDA's repeated disavowal of jurisdiction over cigarettes, with the exception of tobacco products for which a therapeutic benefit (such as to help one lose weight, prevent colds, or inhibit infections) is claimed.[10]

The Supreme Court explained that the original Food and Drug Act of 1906 contained no express reference to tobacco or tobacco products. A 1914 interpretation of the 1906 Act advised that

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[8] *Id.*, 529 U.S. 120 (2000). Due to this determinative Supreme Court decision, the petitioners' reference (at 13) to FDA decisions unrelated to tobacco, such as *U.S. v. An Article of Drug ...Bacto-Unidisk*, 394 U.S. 784 (1969), and *National Nutritional Foods Ass'n v. Weinberger*, 512 F.2d 688, 701-02 (2d Cir. 1975), *cert. denied*, 423 U.S. 827 (1975), have no precedential value. Deference to FDA assertion of jurisdiction over tobacco products would be contrary to the seminal *Brown & Williamson* decision.

[9] *Id.* at 158-159, summarizing the long-standing policy of the FDA (emphasis added).

[10] *See id.* at 131-32, 145. While the Supreme Court decision occasionally uses terms such as "health claims" interchangeably with "therapeutic claims," it is clear that "therapeutic claims" such as claims to lose weight, prevent colds, and inhibit infections were envisioned by the court. The Supreme Court cited the only two decisions that ever upheld FDA jurisdiction over products that contain tobacco, and in both of those decisions therapeutic claims – such as claims to prevent colds, lose weight, or inhibit infections -- were made. In the Petition (at 9), the petitioners cite *ASH v. Harris*, 655 F.2d 236 (C.A.D.C. 1980), and other cases for the proposition that the FDA has jurisdiction over "tobacco products that bear health-related claims." However, none of the cigarette decisions cited by the Supreme Court use the phrase "health-related claims"; this is a more general term, used by petitioners, in an attempt to obfuscate the issue.

tobacco be included under the 1906 Act only when used to cure, mitigate, or prevent disease. [11] Subsequently, as noted by the Supreme Court, although there have been numerous pieces of legislation concerning cigarettes, smoking, and public health that have been enacted by Congress over the last 35 years – none of them have placed cigarettes under FDA jurisdiction.

B. FDA Has Historically Disavowed Jurisdiction Over Cigarettes Without Therapeutic Claims.

1. FDA-Related Judicial Decisions Prior to the Supreme Court's Decision in *Brown & Williamson*.

It is well-established that the FDA has successfully asserted jurisdiction over tobacco cigarettes in only two judicial decisions, one regarding Fairfax cigarettes (making explicit disease prevention claims) and one regarding Trim Reducing-Aids. Both cigarettes were promoted for therapeutic purposes -- such as to support weight-loss and fight the common cold -- and were not promoted solely with product attribute claims.

a. Fairfax Decision.

In 1953, in *United States v. 46 Cartons more or less, containing Fairfax Cigarettes*, 133 F. Supp. 336 (D. N.J. 1953) (*"Fairfax"*), the court held that cigarettes (which contained triethylene glycol) shipped with literature suggesting that the cigarettes were effective in preventing respiratory disease and other diseases came within the term "drug" as used in the Federal Food, Drug, and Cosmetic Act. [12] Specifically, the claims alleged for the Fairfax cigarette included the following:

> The libellant contends that the leaflet accompanying the article suggests and represents that the article is effective in preventing respiratory diseases, common cold, influenza, pneumonia, acute sinusitis, acute tonsillitis, scarlet fever, whooping cough, measles, meningitis, tuberculosis, mumps, otitis media (middle ear infection), meningopneumonitis psittacosis (parrot fever). [In addition, the court found] extensive reference to 'miracle vapor' and its seeming effects in the reduction of the frequency of respiratory diseases, and the somewhat more than casual references to the diseases aforementioned.[13]

According to the court, the key question was "whether the public, having in mind the specious statements of the leaflets, would buy Fairfax cigarettes primarily for smoking enjoyment or with the hope of mitigating, curing or preventing disease."[14] Largely because of the diseases printed

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[11] *See Brown & Williamson* at 146. Also noted in an article entitled *Selected Actions of the U.S. Government Regarding the Regulation of Tobacco Sales, Marketing, and Use*, on the CDC home page, National Center for Chronic Disease Prevention and Health Promotion, http://www.cdc.gov/tobacco/overview/regulate.htm. (*See* Attachment D.)

[12] *See* Section III. C., infra, for a more detailed discussion of this product and its advertising.

[13] *Id.* at 337.

[14] *Id.* (emphasis added).

"throughout" the leaflet, the court found that the thrust of the claimant's literature was appealing to the consumer's hope "to avoid the infectious diseases or ailments therein mentioned."[15] With this reasoning, the court found Fairfax cigarettes to be a drug product.

b. Trim Reducing-Aid Decision.

In 1959, in *United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847 (D. N.J. 1959) (*"Trim Reducing-Aid"*), the Trim Reducing-Aid cigarette was found to be a "new drug" subject to FDA jurisdiction. The cigarettes were promoted for weight loss, as the back of each package contained these specific directions for use:

> Smoke one cigarette shortly before meals . . . and whenever you are tempted to reach for a late evening snack. Trim reducing-aid cigarettes contain a patented appetite satient that takes the edge off your appetite. Clinically tested . . . Trim reducing-aid cigarettes are "Guaranteed" to satisfy you or your money back.[16]

A "display card" further promoting the product stated that appetite suppressing cigarettes "are not intended to replace the purchaser's favorite cigarettes nor to change his present smoking habits" and only three or four of the reducing-aid cigarettes are to be smoked a day, suggesting that the product was not intended to be used as a cigarette at all, but in addition to the consumer's cigarettes -- as a diet pill.[17]

Furthermore, unlike Omni, which simply highlights reduced amounts of certain constituents, the diet cigarettes contained an added ingredient, tartaric acid, which was specifically intended to reduce the appetite. Thus, the court concluded:

> The Trim cigarette involved in this litigation is obviously an article intended to affect the structure and/or function of the human body and contains, as a component, tartaric acid which affects the structure and/or functions of the body. Claimant readily concedes that its product is intended to affect the structure and functions of the human body by reducing the appetite for the ingestion of food and thereby achieving a reduction in the body's weight. The component of the cigarette which the claimant asserts is critically effectual in satiating the appetite is tartaric acid, which is used and intended by the claimant to be used in the composition of its cigarette.[18]

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[15] *Fairfax* at 338 (emphasis added).

[16] *Id.* at 849.

[17] *See id.*

[18] *Id.* at 851.

c. Distinction from Omni Cigarettes.

Fairfax cigarettes and Trim cigarettes are the only cigarettes over which the FDA asserted jurisdiction, and which courts have found to be drugs. Significantly, both products made explicit therapeutic drug claims – such as claims to prevent respiratory diseases, lose weight, and prevent infections. By contrast, Omni cigarettes are intended for smoking pleasure – and bear product attribute claims similar to "light" and "low tar" claims. Moreover, labeling and advertising statements for Omni emphasize that the product is not proven to be safer than other cigarettes -- and emphasize that Omni still contains toxic substances. Even the most strained interpretation of the Omni labels and advertisements would be unable to conclude that Omni cigarettes are promoted for therapeutic purposes that may result in FDA jurisdiction. Indeed, the Omni claims are more tempered and carefully qualified than "low tar" and "light" claims – which ave never, in 50 years, been subject to FDA jurisdiction.

2. FDA Has Acknowledged That The Agency Does Not Have Jurisdiction Over Tobacco Products – Including Tobacco Products That Bear Product Attribute Claims.

There is a long history of cigarette products bearing product attribute claims – such as "low tar," "mild," "soothing," and "light" -- not being subject to FDA jurisdiction. Specifically, tobacco companies have appealed to the health interests of smokers since at least 1927, and representations about lower tar levels appeared as early as 1942.[19] In many cases, the new products and brands, especially in the 1950s when filters were first popular, were touted as safer and as reducing some of the harmful components in cigarette smoke.

Importantly, the FDA has never asserted jurisdiction over tobacco products solely accompanied by product attribute claims (such as low tar, light, and low carcinogen claims). The Institute of Medicine recently noted: "When filtered and low-yield cigarettes were introduced into the U.S. markets, they were heavily promoted and marketed with both and explicit and implicit claims of reducing the risk of smoking."[20] The Institute of Medicine report notes that tobacco companies since at least 1927 have appealed to the health concerns of smokers with low tar and low nicotine claims, as well as general product attribute claims, such as "filtered cigarette smoke is better for your health" (Viceroy, 1951), without assertions of jurisdiction by the FDA.[21]

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[19] *See Clearing the Smoke*, Institute of Medicine Report (2001) ("IOM Report") at 3-1.

[20] IOM Report at 3-1.

[21] *See* IOM Report at 3-1 - 3-3, 3-13 - 3-16 (Table 3-1, listing selected advertising messages for cigarettes and potential reduced exposure products). (*See* Attachment E.)

a. FDA's Rejection of the Citizen Petition Filed by Action on Smoking and Health Proposing that FDA Regulate Filtered Cigarettes.

The FDA has never asserted jurisdiction over tobacco-containing cigarettes marketed for their filters or "low tar" or "low nicotine" properties alone, despite the fact that the Coalition on Smoking or Health ("CSH") and Action on Smoking and Health ("ASH") have filed multiple petitions requesting that FDA do so. For example, in 1978, ASH filed a petition arguing that FDA should regulate filtered cigarettes because they were sold and used with an intent to mitigate disease. FDA, however, rejected that petition,[22] and stated that product attribute claims -- even claims designed to highlight features of specific cigarettes that may make them less hazardous to smoke -- do not result in FDA jurisdiction.[23]

Specifically, the Agency indicated that "[w]here, as here, attached filters are at most represented as making the cigarettes to which they are attached less hazardous to smoke, neither the cigarettes nor the filters are thereby intended for use in the mitigation, treatment, or prevention of disease." [24] FDA explained that filter claims to reduce exposure to hazardous constituents of cigarettes, and to create a "safer" cigarette, do not bring such filters or cigarettes within the Agency's jurisdiction. The agency explained that: "[r]epresentations in cigarette labeling or advertising . . . as to the absolute or *relative quantity* of hazardous constituents of cigarette smoke or as to the safety of the cigarettes do not make the cigarettes or their filters intended for use in the mitigation, treatment, or prevention of disease."[25] FDA reasoned as follows:

> [A] claim of general or comparative safety, without more, will not usually cause a product to be subject to the Act. Many products are designed and sold to be used to reduce the exposure of humans to hazardous substances. For example, catalytic converters and lead-free gasoline for use with automobiles are designed to reduce the exposure of humans to lead and hazardous by-products of gasoline combustion. These products, however, are not deemed to be within the Agency's jurisdiction. The determination that a product is properly regulated under the Act is not left to FDA's unbridled discretion but must be in accordance with the statutory definition.[26]

In addition, in 1988, CSH petitioned FDA to regulate cigarettes with low tar and low nicotine claims, arguing that such claims had no purpose other than to promote these cigarettes as safer and

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[22] *See* Letter from Mark Novitch, Acting Comm'r Food & Drugs, FDA, to John F. Banzhaf III, Executive Dir., ASH & Peter Georgiades, ASH, at 8 (Nov. 25, 1980) ("1980 FDA letter"). (*See* Attachment F.)

[23] 1980 FDA letter at 8.

[24] *Id.*

[25] *Id.* at 8 (emphasis and italics added).

[26] *Id.* at 11.

less addictive and to create that perception in the public.[27] This petition was later amended after the development of R.J. Reynolds' Eclipse™ smokeless cigarette and Philip Morris' denicotinized NEXT™ cigarette. FDA did not respond to those petitions until 1994, at which point the Agency acknowledged the existence of several petitions concerning such products. FDA, however, neither granted nor denied the requests, and indicated that the Agency was reconsidering its assertion of jurisdiction over tobacco products generally.[28]

b. Omni Cigarettes.

FDA's historical position toward tobacco and cigarettes, and the agency's rejection of the 1978 ASH Citizen Petition and 1988 CSH Citizen Petition, clearly support the absence of FDA jurisdiction over Omni cigarettes. Specifically, as noted by the FDA in its rejection of the ASH Citizen Petition, representations in cigarette labeling or advertising regarding the reduction of hazardous constituents in cigarette smoke (and even representations as to the safety of a cigarette) do not make the cigarettes or their filters intended for use in the mitigation, treatment, or prevention of disease. The FDA also noted that the Agency would not have jurisdiction over cigarettes even if they bear claims of general or comparative safety.

As noted, Omni bears product attribute claims that are simply a more scientifically substantiated variation on claims made for cigarettes for over 50 years – such as "light" and "low tar" claims – which have never resulted in FDA jurisdiction. "Reduced carcinogen" or reduced hazardous constituent claims – as the FDA noted in rejecting the ASH Citizen Petition – are not, and should not be, subject to FDA jurisdiction.

III. The Products Subject to FDA Jurisdiction, And Cited By The Petitioners, Actually Support The Absence of FDA Jurisdiction Over Omni Cigarettes.

The three products referenced by the petitioners are entirely distinguishable from Omni cigarettes -- and actually confirm the absence of FDA jurisdiction over cigarette products such as Omni. Two of the products discussed by the petitioners -- Jazz cigarettes and GumSmoke -- do not contain tobacco, and therefore are entirely irrelevant (as products that do not contain tobacco are not governed by Congressional preemption or the Supreme Court's *Brown & Williamson* decision). The third product, Fairfax cigarettes, is also entirely distinguishable from Omni in that it contained therapeutic claims to treat a wide array of diseases (which clearly constituted drug claims that should – and did – result in FDA jurisdiction).

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[27] *See* FDA Doc. No. 88P-0155/CP (Apr. 25, 1988).

[28] *See* Letter from David Kessler, FDA Commissioner, to Scott Ballin, Chairman, CSH (Feb. 25, 1994), in Regulation of Tobacco Products: Hearings Before Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce, 103d Cong., 2d Sess. 149 (1994). (*See* Attachment G.). Further, FDA has not asserted jurisdiction, even on a case-by-case basis, over currently marketed cigarette-like products that contain tobacco, such as Eclipse™ (a reduced smoke cigarette containing reconstituted tobacco, which makes a multitude of claims) and Advance™ (a tobacco-containing cigarette claiming that it has lower levels of nitrosamines). *See* IOM Report at 4-11.

A. Unlike Omni, Jazz Did Not Contain Tobacco, Was Marketed As A Smoking Cessation Product, And Therefore Was Clearly Subject To FDA Jurisdiction.

Although the Petition presents Jazz as a tobacco cigarette comparable to Omni, and although the one-page promotional piece on Jazz attached to the Petition states in a bullet point, "REAL TOBACCO," Jazz was actually a non-tobacco cigarette presented as a alternative to be used to quit smoking.[29] The Jazz cigarette and its claims are entirely distinguishable from the Omni cigarette in the following ways:

1) Jazz is a non-tobacco cigarette.
2) Jazz is presented as an alternative to tobacco cigarettes.
3) Jazz was labeled and intended for use as a smoking cessation product, based on several statements.
4) One claim was: "Jazz will not hurt you like other cigarettes."
5) The one-page flyer proclaimed, in large letters: "The Luxury of Smoking Without Worrying."
6) This flyer also states: "Show your concern . . . send this healthy product to a friend or relative who enjoys smoking." [Emphasis added.]
7) Both the labeling and promotional material claimed Jazz would produce "No Health Hazard."[30]
8) The labeling and promotional material blatantly and in capital letters claimed Jazz was "A SAFE CIGARETTE . . . NO CANCER."

Based upon the above, Jazz is not remotely comparable to Omni and, therefore, not relevant to, and unsupportive of, petitioner's contention that Omni cigarettes should be subject to FDA jurisdiction.

B. Unlike Omni, GumSmoke Did Not Contain Tobacco, And Was Promoted As A Smoking Cessation Gum Product, Resulting in FDA Jurisdiction.

The GumSmoke product is not a cigarette, is not smoked and does not contain any tobacco; it is a gum that is merely tobacco flavored. In all three GumSmoke ads, the tag line underneath the product name reads in capital letters: "When you can't smoke." Two of the ads warn "Underage Sale Prohibited" and state "5 Sticks; Gum for Smokers." In a third ad for GumSmoke, the ingredient list begins: "sugar, chewing gum base, corn syrup, dextrose" and the consumer is invited to write to Star Tobacco & Pharmaceuticals "For nutritional information," as for a food.

Indeed, it was the candy, non-cigarette form of the product (i.e., a gum) that caused the most concern for the FDA. In a July 22, 1998 letter to Star Tobacco, FDA expressed the Agency's "concerns" with the new product. As an initial matter, it is important to observe that Star Tobacco described GUMSMOKE as a tobacco-flavored chewing gum, which would be marketed as a "confection." Containing no tobacco or nicotine, the product is not a cigarette at all, and certainly not a tobacco cigarette. The FDA's concerns refer not to any reduced-component claims or to

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[29] *See* Jazz discussed in an FTC enforcement action below. *In the Matter of Alan V. Phan*, Agreement Containing Consent Order to Cease and Desist, No. 922-3155, 1992 WL 69728 (F.T.C.), Sept. 29, 1992.

[30] *See* Attachment M of Petition.

harmful constituents that may remain in a tobacco product that is heated and smoked. Indeed, the Agency's concerns are not about the GUMSMOKE product itself, nor any harmful effects, but about its name and possible consumer misconceptions that the name might engender:

> . . . we are very concerned that the name, label, and promotional materials associated with the product may create the perception that GUMSMOKE is a milder, safer form of smokeless tobacco or a milder, safer substitute for smoking conventional cigarettes. Alternatively, tobacco users may perceive GUMSMOKE as a safer, inexpensive substitute for FDA-approved smoking cessation products, especially the over-the-counter drug product NICORETTE (nicotine polacrilex gum).[31]

Nowhere in this letter about a non-tobacco, non-smoked, candy-like gum is there any mention of concern that reduced-risk claims are in fact disease-prevention claims, and thus that the product fits under FDCA's "drug" definition. Instead, the most serious concern is that consumers may perceive GumSmoke as an alternative either to a conventional cigarette or to a smoking cessation product. Given all the contrasts and distinctions above, the example of the FDA's position on GumSmoke is not analogous, but inapposite. FDA's letter regarding the proposed marketing of GumSmoke does not advance the argument of the petitioners or provide any precedent for FDA jurisdiction over Omni.

C. Unlike Omni, Fairfax Cigarettes Were Promoted With Explicit Therapeutic Benefit Claims.

Of the three products presented by petitioners as being allegedly comparable to Omni, only one of the products contained tobacco. Although Fairfax Cigarettes contained tobacco, however, they also contained an added ingredient – triethylene glycol – and the cigarettes were promoted with numerous claims of therapeutic benefit. In fact, Fairfax cigarettes were advertised as the miracle drug of the century.

The claims in the two-page flyer advertisement for Fairfax cigarettes [32] were voluminous. The first paragraph of the advertisement, for example, provided the following:

> This is the story of how science discovered a "miracle vapor" that seems to reduce the frequency of respiratory diseases, including the "common cold," and how the results of these findings can benefit you not only in hospitals and laboratories but in your everyday life – *even in the cigarette you smoke.*[33]

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[31] *See* Attachment N of the Petition (emphasis added).

[32] Attachment K of the Petition. (*See* Attachment H.)

[33] *Id.* (italics in the original; emphasis added).

The advertisement indicated that Fairfax cigarettes are "moistened" with triethylene glycol. The advertisement then made the following therapeutic statements:[34]

1. War time has led to "rapid progress in many fields of medicine."
2. "One field of medicine [producing] a tremendous impetus to research was the field of the so-called 'common cold' and other air-borne infections."
3. Conditions in the air-raid shelters in England "caused British doctors and scientists to . . . find a means of preventing the transmission of various contagious diseases."
4. "Their work led to the discovery of the power of triethylene glycol vapor [used in Fairfax] as a killer of air-borne bacterial and virus."
5. The U.S. Commission on Air-Borne Infections conducted many tests of triethylene glycol vapor and found that a small amount "killed many virus [sic] and bacteria."
6. In one test triethylene glycol vapor "killed 85% of the . . . scarlet fever bacteria instantly."
7. "In another test, mice were placed in laboratory test chambers which had been vaporized with triethylene glycol. A lethal dose of influenza virus was sprayed into the test chambers. The mice were completely protected."
8. Many other tests "indicated that triethylene glycol vapor is capable of killing or inactivating most of the bacteria and virus [sic] listed below."
9. In the box following that sentence, the right-hand column "indicates the human diseases generally considered to be transmitted by them." [What follows in the flyer is a list of the 13 diseases cited in the *Fairfax* opinion that Fairfax cigarettes were claimed to prevent.]

Overall, the promotional flyer for Fairfax cigarettes consisted of two pages of dense printing in small font size describing the medical research and therapeutic benefits of the cigarettes.

D. Omni Cigarettes Contain Tobacco, And Are Not Promoted For Therapeutic Benefit.

In stark contrast to all three of the products described by the petitioners and analyzed above, Omni is not a gum or a candy, is not a smoking cessation product and does not claim to cure influenza and/or other diseases. Indeed, Omni has almost nothing in common with the three products cited by petitioners as purported precedents for FDA jurisdiction.

Unlike two of the three products cited as analogs, Omni does contain tobacco – and therefore is subject to the Supreme Court's *Brown & Williamson* decision. Moreover, as a cigarette as customarily marketed, with no therapeutic benefit claims, Omni is jurisdictionally a variant on the many "low tar" and "light" cigarettes marketed in the United States for the past 50 years. Accordingly, the cases cited by the petitioners, in fact, support the conclusion that Omni cigarettes are not subject to FDA jurisdiction.

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[34] *Id.* (citations omitted; bold type added).

IV. The Presidential Commission on Tobacco Has Indicated That FDA Does Not Have Jurisdiction Over Cigarettes Such As Omni.

On May 14, 2001, the President's Commission on Tobacco issued its final report, and it too reinforces the position that reduced-exposure cigarettes are not under FDA's jurisdiction. *See Tobacco at a Crossroad, A Call for Action: Final Report of the President's Commission on Improving Economic Opportunity in Communities Dependent on Tobacco Production While Protecting Public Health ("President's Commission Report")*. Chapter 5, Section 3 of the *President's Commission Report* made several public health proposals, including a proposal that Congress grant FDA authority over tobacco products that is comparable to FDA's authority over other products (*i.e.*, manufacture, sale, marketing, distribution, and labeling).[35]

As part of the proposal, the Commission implicitly recognized that FDA does not currently have any authority over reduced-exposure tobacco products by recommending that Congress grant FDA "authority over products that purport to reduce consumer health risks or serve as less harmful alternatives and the authority to evaluate scientifically whether these products are actually 'less harmful' taking into consideration both individual consumers and the population as a whole."[36] Significantly, the Commission stated that FDA's authority over reduced-exposure tobacco products should be modified to include the power to "prohibit or restrict unsubstantiated health claims and false or misleading claims,"[37] but not the authority to ban the use of these or any other tobacco products.[38]

V. There Are Sound Public Policy Reasons for FDA to Reject the Petition.

A. Cigarettes With Reduced Carcinogens Should Be Encouraged – As Should Research To Develop Alternative Cigarettes.

There are sound public policy and public health reasons to reject FDA jurisdiction of Omni cigarettes. FDA jurisdiction of Omni as a drug would presumably mean a ban on these cigarettes. Thus, a reduced carcinogen cigarette would be taken off the market, leaving on the market and in smokers' hands many other types of cigarettes with greater amounts of carcinogens. Interpreting *Brown & Williamson* and Congressional intent so as to result in such a ban would therefore be misguided and counterproductive from a public health perspective. Reduced carcinogen cigarettes should not be singled-out for FDA jurisdiction, while other cigarettes remain available to the population. Rather, reduced carcinogen cigarettes should be regulated in the same manner as all other cigarettes sold in the United States.

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[35] *See President's Commission Report* at 42.

[36] *Id.* at 46.

[37] *See id.*

[38] *See id.* at 42.

B. Omni Cigarettes, Like All Cigarettes, Are Highly Regulated.

Tobacco cigarettes have been stringently regulated, largely by the FTC, in a manner dictated by Congress, for over 35 years. The impetus for the legislation that became the Federal Cigarette Labeling and Advertising Act of 1965 ("FCLAA") was the Surgeon General's Report of 1964, which concluded that there was a strong cause and effect relationship between cigarette smoking and serious health risks. Tobacco cigarettes are a unique product in American commercial history, as recognized by Congress in the first section of the FCLAA:

> It is the policy of the Congress, and the purpose of this chapter, to establish a comprehensive Federal Program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby –
>
> (1) the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes; and
>
> (2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health.[39]

Balancing these dual goals of protecting the economy (given the important role of the tobacco industry in the U.S.) and safeguarding the health of the American public, Congress clearly intended to allow the sale of cigarettes in the U.S. but to require adequate warnings for public health reasons, and also to craft a uniform and consistent framework for labeling and advertising of cigarettes. In *Brown & Williamson*, the Supreme Court cited the FCLAA as rendering FDA regulation of conventional cigarettes logically and legally impossible:

> Congress' decisions to regulate labeling and advertising and to adopt the express policy of protecting "commerce and the national economy . . . to the maximum extent" reveal its intent that tobacco products remain on the market. Indeed, the collective premise of these statutes is that cigarettes and smokeless tobacco will continue to be sold in the United States. A ban of tobacco products by the FDA would therefore plainly contradict congressional policy.[40]

The original compulsory warning was a general one: "Caution: Cigarette Smoking May Be Hazardous to Your Health." However, with the Comprehensive Smoking Education Act of 1984, Congress refined the language into four different warnings to be used on a rotating basis. Section 1333 of the FCLAA now mandates the use of one of four Surgeon General Warnings on packages and advertisements for cigarettes, with slightly abbreviated phrasing required for these warnings on

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[39] *See* 15 U.S.C. §1331 (emphasis added).

[40] *Id.*, 529 U.S. 120, 138-39.

outdoor billboards[41] and includes very precise requirements for the conspicuousness, type size, and label format for this language.[42] Further, the FCLAA requires manufacturers and importers to submit a packaging and advertising plan for FTC approval.[43] Finally, the manufacturer's plan must assure an even distribution of the warning statements in all parts of the U.S. where product is sold.[44]

In addition, Congress delegated responsibilities to the FTC regarding labeling (testing and monitoring of tar and nicotine, and reporting to Congress) and also delegated authority to the FTC to monitor deceptive advertising. But it is significant that as to packaging, only the health statements required by section 1333 (the four Surgeon General's Warnings, in rotation) may be required -- by any Federal or state regulatory agency (including the FDA). Other label requirements are preempted, further indicating the intention of Congress that cigarettes that include product attribute claims such as "low tar" claims and the claims used for Omni, are not subject to FDA jurisdiction.

As noted by the Supreme Court in *Brown & Williamson*, with regard to tobacco, FDA has repeatedly deferred to Congress, which has pre-empted the field of cigarette labeling and advertising. The sole exception recognized by FDA, Congress, and the Supreme Court is for cigarettes that bear therapeutic claims. Product attribute claims, such as the claims used on Omni labeling and advertising, and by manufacturers of "low tar" and "light" cigarettes for over 50 years, clearly fall outside FDA jurisdiction.

C. The FTC Should Be the Primary Government Agency to Regulate The Promotion of Tobacco Products Such as Omni.

1. Regulatory Authority.

The Federal Trade Commission (FTC) Act of 1914, amended in 1938, empowers the FTC to "prevent persons, partnerships, or corporations . . . from using unfair or deceptive acts or practices in commerce." Specifically, with regard to the promotion of cigarettes, in January 1964, the FTC proposed a rule to strictly regulate the imagery and copy of cigarette ads to prohibit explicit or implicit health claims. This action prompted Congress to pass the FCLAA, which in turn granted regulatory powers over cigarette claims to the FTC, not to the FDA.[45]

Section 1336 of the FCLAA, entitled "Authority of Federal Trade Commission; unfair or deceptive acts or practices," expressly states: "Nothing in this chapter (other than the requirements of section 1333 of this title) shall be construed to limit, restrict, expand, or otherwise affect the authority of the

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[41] *See* 15 U.S.C. § 1333(a).

[42] *See* 15 U.S.C. § 1333(b).

[43] *See* 15 U.S.C. § 1333(c).

[44] *Id.*

[45] *See Brown & Williamson* at 146-49.

Federal Trade Commission with respect to unfair or deceptive acts or practices in the advertising of cigarettes." As detailed below, the FTC has been extremely active in monitoring and prosecuting misleading and deceptive promotional claims for cigarettes.

2. FTC Judicial Precedent: Product Attribute Claims.

For over 50 years, cigarettes have been marketed with product attribute claims – such as "low tar," "light," "medium," extra light," "ultra light," "ultra low," and "ultima." While the FTC has not established *official* definitions for these terms,[46] such terms generally reflect ranges of FTC tar ratings.[47] For example, the terms "low tar" and "light" generally refer to cigarettes with tar ratings that range from 6-15 milligrams ("mg") and the terms "ultra low tar" and "ultra light" generally refer to cigarettes with tar ratings of 6 mg or less.[48] "Regular" cigarettes, in contrast, generally have a tar rating of more than 15 mg.[49] Notably, in 1998, 81.9% of cigarettes consumed in the United States had a tar rating of 15 mg or less. [50]

Product attribute claims such as "low tar" and "light" have never converted a cigarette product into a drug. In fact, in the only judicial ruling on this issue, *FTC v. Liggett & Myers*,[51] the court held that representations about a cigarette product's lack of adverse effects do not constitute therapeutic claims and do not render cigarettes a drug. In that case, an action for false advertising was brought by the FTC under the Federal Trade Commission Act, which incorporates the same definition of "drug" as in the Federal Food, Drug, and Cosmetic Act.

The issue was whether advertising claims that Chesterfield cigarettes "can be smoked by a smoker without inducing any adverse affect upon the nose, throat and accessory organs of the smoker" (in the FTC's interpretation) constituted false advertising. The lower court rejected the FTC's contention that the Chesterfield cigarettes at issue were drugs because they were represented, according to the FTC, as manufactured so as to "prevent irritation of the nose, throat and accessory organs of smokers."[52] The court reasoned that to be a drug, a product would have to claim an affirmative therapeutic benefit. The court's rejection of the FTC's allegation of a "prevention" claim is also significant:

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[46] *See* 62 Fed. Reg. at 48163; *see also* IOM Report, at 3-5.

[47] *See* 62 Fed. Reg. at 48163; IOM Report at 3-5.

[48] *See* 62 Fed. Reg. at 48163 (reporting that "low tar" generally refers to a tar rating of 7-15 mg and that "ultra low tar" generally refers to a tar rating of 6 mg or less); IOM Report at 3-5 (reporting that "light" generally refers to a tar rating of 6-15 mg and that "ultra light" generally refers to a tar rating of 1-5 mg).

[49] *See* IOM Report at 4-5.

[50] *See id.* at 3-5.

[51] 108 F. Supp. 573 (S.D.N.Y. 1952), *aff'd* 203 F.2d 955 (2d Cir. 1953).

[52] *Id.* at 574.

> If this allegation were construed as a charge that the defendant affirmatively claimed a therapeutic purpose of Chesterfield cigarettes we would have to await trial. But this is not the case here. It is true, that cigarettes have, in the past, been placed on the market and advertised as having therapeutic purposes [citing *Fairfax*]. [But that is totally different] from a representation by the defendant of a 'non-adverse' rather than beneficial effect.[53]

Thus, the lower court held that a representation of a "non-adverse" effect did not make a cigarette a drug, and the Second Circuit affirmed.[54]

VI. Conclusion – Omni Cigarettes Are Not Subject To FDA Jurisdiction.

The Supreme Court, in the seminal *Brown & Williamson* decision, held that cigarettes as customarily marketed (including cigarettes bearing product attribute claims) are not subject to FDA jurisdiction. The Supreme Court emphasized that Congress precluded FDA's jurisdiction to regulate tobacco products in the absence of the type of therapeutic benefit claims that led to FDA jurisdiction in the past (i.e., therapeutic claims such as claims that cigarettes can help one lose weight, prevent colds, or inhibit infections).[55]

As explained above, Omni cigarettes are labeled and advertised with product attribute claims – and do not contain any therapeutic claims. There is a long history in the United States of cigarettes being marketed with product attribute claims -- such as low tar and light claims – and such products have never been subject to FDA jurisdiction. Rather, as with all cigarettes, such products have been regulated in accordance with the detailed, cigarette-specific framework set in place by Congress, with extensive powers delegated to and exercised by the FTC and other regulatory bodies.

If FDA were to assert jurisdiction over cigarettes (such as Omni) bearing product attribute claims, it would do so in conflict with Congressional dictate, Supreme Court mandate, and past FDA precedent on this issue. In addition, FDA assertion of jurisdiction would in practice ban the use of reduced carcinogen cigarettes – while leaving cigarettes with higher carcinogen levels on the market. Accordingly, interpreting *Brown & Williamson* and Congressional intent so as to result in such a ban would be misguided and counterproductive.

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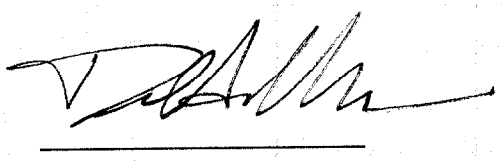
[53] *Id.* at 575 (emphasis added).

[54] *FTC v. Liggett & Myers*, 108 F. Supp. 573 (S.D.N.Y. 1952), *aff'd* 203 F.2d 955 (2d Cir. 1953) (no opinion published).

[55] *Brown & Williamson*, 529 U.S. 120, 150-53 (citing *ASH v. Harris*, 655 F.2d 236, 239 n.7 (C.A.D.C. 1980), citing *United States v. 46 Cartons more or less, containing Fairfax Cigarettes*, 133 F. Supp. 336, (D. N.J. 1953) ("*Fairfax*") and *United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847 ((D. N.J. 1959) ("*Trim Reducing-Aid*")). The Supreme Court cited two decisions that upheld FDA jurisdiction over products that contain tobacco, and in both of those decisions therapeutic claims – such as claims to prevent colds, lose weight, or inhibit infections -- were made.

For the foregoing legal and public policy reasons, we request that the Food and Drug Administration reject the above-referenced Citizen Petitions and reconfirm that FDA does not have jurisdiction over cigarettes such as Omni.

Respectfully submitted,



Stuart M. Pape
Daniel A. Kracov
Paul D. Rubin

PATTON BOGGS LLP
2550 M Street, N.W.
Washington, D.C. 20037
(202) 457-6000
Counsel to Vector Tobacco Inc.